K092507

510(k) Summary of Safety and Effectiveness
May 11, 2010

MAY 11 2010

Submitted by: Steffen Kahdemann
Managing Director

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Classification Name: Endosseous dental implant 21 CFR 872.3640

Trade Name: zit-z Dental Implant System

Legally Marketed Device: NobelBiocare Zirconia Implant K061971 and Z-systems Z-Look3 K062542

Device Description:

Zit-z Dental Implant System is a root-form dental implant system with a one-piece cylindrical screw implant design. They have a pentagonal geometry anti-rotation feature which also provides ease of insertion. They are made from HIP zirconium dioxide ceramics (3Y-TZP) which meets ISO 13356.

Indications for Use:

Zit-z dental implants are root-form endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. They are indicated for single or multiple unit restorations in splinted or non-splinted applications. The zit-z dental implants are restored with fixed/cemented crowns and bridges. Not for immediate loading.

The 3.5mm implant is contraindicated for restorations of the posterior teeth in the upper or lower jaw and for single-tooth restoration of canines and central incisors in the upper jaw.

Testing:

Fatigue testing according to ISO 14801 was completed satisfactorily. Canine data was submitted. Successful clinical case study data was provided along with some cases of human histology. The nonclinical and clinical data show the implants can be used successfully and will withstand the fatigue forces necessary for their use. The predicate device Z-Look3 has been used successfully clinically for several years and has not been found to have fatigue issues either.

Technological Comparison:

Characteristic	Zit-z	Z-Look3
Design	One-piece screw implant	One-piece screw implant
Material	Y-TZP	Y-TZP
Implant Diameter	3.5, 4.0, 5.0	3.25, 4.0, 5.0
Implant Length	10, 11.5, 13	10, 11.5, 13, 14
Transgingival Height of Implant	1.5, 2.5	N/A

Substantial Equivalence:

Zit-z implants are of the same material (zirconia) and of similar design (one-piece screw-type implant) as Nobel Biocare's ceramic implant and the Z-Look3. The Y-TZP powders in the predicate devices are prepared via coprecipitation of yttria and zirconia powders, but the Y-TZP used in zit-z is prepared by a newer method coating zirconia grains with yttria. The diameters and lengths available are within the range cleared for Z-Look3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Steffen Kahdemann
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MAY 11 2010

Re: K092507
Trade/Device Name: Zit-z
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 19, 2010
Received: April 23, 2010

Dear Mr. Kahdemann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092507

Device Name: zit-z

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Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Ken Hudy for MSR

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K092507